General

Guideline Title

Diagnosis of breast disease.

Bibliographic Source(s)

Institute for Clinical Systems Improvement (ICSI). Diagnosis of breast disease. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2012 Jan. 45 p. [65 references]

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Diagnosis of breast disease. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2010 Jan. 47 p. [65 references]

Recommendations

Major Recommendations

Note from the National Guideline Clearinghouse (NGC) and the Institute for Clinical Systems Improvement (ICSI): For a description of what has changed since the previous version of this guidance, refer to Summary of Changes Report – January 2012. In addition, in 2011 ICSI began its transition to the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system as a method of assessing the quality of evidence and writing recommendations.

The recommendations for the diagnosis of breast disease are presented in the form of a table with a list of evidence-based recommendations and six algorithms with a total of 69 components, accompanied by detailed annotations. Algorithms and the table are provided in the original guideline document. Algorithms are provided for Evaluation by Primary Care of Patient with Symptoms of Potential Breast Disease (Main Algorithm), Evaluation of Breast Mass, Evaluation of the Breast for Nipple Discharge, Evaluation of Breast Pain, Radiologic Evaluation of the Breast, and Image-Directed Core Needle Biopsy. Clinical highlights and selected annotations (numbered to correspond with the algorithm) follow.

Quality of evidence (Low Quality, Moderate Quality, and High Quality) and strength of recommendation (Weak or Strong) definitions are provided at the end of the "Major Recommendations" field.

Clinical Highlights

- It is imperative that communications between the radiologic and surgical consultants and the primary care clinician are thorough and consistent. (*Annotation #20*)

- Patients with a bloody or clear discharge should be referred to a radiologist and/or surgeon for further evaluation. (*Annotations #35; Aim #2*)
- A persistent mass with negative imaging does not rule out malignancy and requires a referral to a surgeon. (*Annotations #20, 23*)
- Abnormal pathologic findings from image-directed biopsy require a surgical consultation and possible excisional biopsy. (*Annotation #63, 66; Aim #4*)

Evaluation by Primary Care of Patient with Symptoms of Potential Breast Disease Algorithm Annotations

2. Perform History and Physical Exam for Breast-related Symptoms and Assess Risk Factors
   Recommendation:

   - A clinical breast exam should be performed in the presence of breast-related symptoms. *(strong recommendation, low quality evidence)*

   See also Annotations #31, "Patient Presents with Nipple Discharge," and #40, "Patient Presents with Breast Pain," (below) for specific symptom-related history and physical.

   Guidelines for primary care evaluation are initiated with a history aimed at uncovering and characterizing any breast-related symptoms. Likewise, a risk assessment should also be undertaken for identified risk factors: personal history of any breast cancer, personal history of ductal hyperplasia with atypia on previous breast biopsies, or family history of breast cancer in first-degree relatives. A high-risk patient would be one with a mother, sister, or daughter who had breast or ovarian cancer before age 50, or a history of prior radiation before age 30, or is a carrier of mutated breast cancer genes. She should be referred for genetic counseling and consider testing.

   A physical examination should include inspection of the breast for any evidence of ulceration or contour changes. This includes examining the nipple for Paget's disease, and the presence of breast nodule(s), nipple disease, evidence of infection, and/or spontaneous discharge. Palpation should be performed both in the upright and supine position to determine the presence of a palpable mass. Abnormalities detected during a clinical breast examination – such as masses or nodules, nipple discharge, or inflammatory changes – require thorough evaluation and prompt treatment.

9. Is Screening Mammogram Due?
   Recommendations:

   - Screening mammogram must be recommended every one-two years for women ages 50 to 75 years *(strong recommendation, moderate quality evidence)*
   - Screening mammograms could be recommended to women ages 40 to 49 and over the age of 75 *(weak recommendation, moderate quality evidence)*.

   Following completion of a physical examination in which no palpable mass is identified, a routine screening mammogram should be obtained if one has not been done within the recommended interval.

   Regular mammographic screening has been shown to reduce mortality in breast cancer. The results of the mammogram are provided to the primary care physician for reporting to the patient. Screening mammogram must be recommended every one-two years for women ages 50 to 75 years. Screening mammograms could be recommended to women ages 40 to 49 and over the age of 75. All women over age 40 should routinely be given the opportunity to receive information about breast cancer screening and informed decision-making.

   See Appendix A, "Breast MRI," in the original guideline for information on screening high-risk patients.

12. Complete All Radiologic Recommendations
    Should any abnormality be uncovered, it will be the responsibility of the radiologist to complete any additional imaging studies required for the complete radiographic characterization of the lesion. The radiologist should make certain that all recommendations including additional views, follow-up films, ultrasounds, etc., have been completed prior to referral to surgery. However, it is important that the provider ordering the mammogram review the results of these studies to fully understand the impression of the radiologist and to assure that all recommendations by the radiologist have been completed within the department of radiology. Should the recommendation be made by radiology that a surgical consultation is warranted, it will be the responsibility of the primary care provider to establish this referral.

    See Algorithm IV, "Radiologic Evaluation of the Breast," in the original guideline document.

13. Reassure Patient and Inform of Next Screening Date
    Refer to Annotation #9, "Is Screening Mammogram Due?," for recommended mammography screening intervals.

I. Evaluation of Breast Mass Algorithm Annotations

15. Is There a Dominant Mass?
    A dominant mass is a palpable finding that is discrete, solid, and clearly different than the surrounding parenchyma. Should a palpable mass be identified, it should be characterized as to whether it represents a dominant (i.e., discrete) mass that requires immediate evaluation. Should physical examination demonstrate a palpable mass that is not clearly discrete and dominant (indeterminate), its size, location, and character should be documented in anticipation of follow-up examination.

16. Perform Diagnostic Mammogram and Ultrasound if Patient ≥30; Ultrasound if Patient <30
    Recommendation:

    - A mammogram and ultrasound should be obtained for patients with a breast mass. Patients under the age of 30 should receive an ultrasound *(strong recommendation, low quality evidence)*.

    Prior to the referral, a mammogram should be obtained. Patients under the age of 30 should receive an ultrasound. For women under age 50, digital mammography is preferable for dense breast tissue. Also see Annotation #50, "Abnormal Screening or Diagnostic Mammogram."

20. Refer to a Surgeon
    Patients referred to the department of surgery for evaluation of breast disease will have undergone previous mammography that has demonstrated an abnormality that has been worked up and requires further surgical intervention, or the patient may be referred on the basis of a physical finding uncovered in the primary care clinician's office. It is the role of the surgeon to evaluate each and every abnormality uncovered in each patient. It is important for the surgeon to recognize that mammographically depicted lesions and palpable abnormalities may coexist as separate entities within the breast. It is therefore important that each lesion be evaluated for its own merit, using this algorithm.

    The importance of communication between the surgical consultant and the primary care clinician cannot be overstated. Patients undergoing biopsy should have results reported both to the surgeon and the primary care clinician. More importantly, patients who do not require biopsy following surgical consultation should be returned to the routine screening process only after the surgeon has completed full evaluation, including any interval follow-up exams, and is satisfied that the symptom does not represent malignancy. For example, if the surgeon feels that the symptom should be followed up in six months to document stability, this follow-up visit should take place with the surgeon. Once the surgeon is satisfied that no further follow-up is needed, the patient may return to routine screening. This process is under the supervision of the primary care clinician. Therefore, it is absolutely necessary for the primary care clinician to know when the patient reenters the routine screening population. In the event that new symptoms arise or occur during the screening interval, the patient should be evaluated by the primary care physician using the primary care evaluation process stated in Algorithm I, "Evaluation of Breast Mass."

23. Residual Mass or Bloody Aspirate?
    Recommendation:

    - Patients with a residual mass or a bloody aspirate should have an image-directed core biopsy or surgical consult *(strong recommendation, low quality evidence)*.

    A simple cyst is one that resolves with aspiration of non-bloody fluid. If fluid is clear and non-spontaneous (e.g., as in compression mammogram), a workup is not always necessary, as this is benign. Surgical excision should be performed for those cysts with bloody aspirates and those that do not completely resolve with aspiration. A cyst that recurs may be re-aspirated, but the number of times this procedure can be repeated without surgical excision will depend upon the surgeon and patient's level of confidence that the lesion is benign.

    Non-bloody fluids should be discarded, based on a study where no cancers were detected among 6,747 non-bloody specimens.

    Among 401 patients with cystic masses, only four had cancer and all had either bloody fluid or a residual mass. This would be demonstrated by palpation or imaging.

    Should the mass remain following the attempt at aspiration or should a bloody aspirate be obtained during the process, the presence of a malignancy cannot be ruled out. Patients with a residual mass or a bloody aspirate should proceed to image-directed core biopsy or surgical consult.

    Bloody aspirate should be considered for cytology.

24. Return for Evaluation for Recurrence or Enlarging Mass
    If no residual mass or blood aspirate remains, a repeat examination should be performed in 4 to 6 weeks at the discretion of clinician. The optimum time for this exam is after one menstrual cycle.

28. Is There a Dominant Mass?

Refer to Annotation #15 for further information.

29. Inform Patient of Next Screening Date
    If no mass is apparent at the time of this examination, the patient should be informed of the appropriate date of her next routine screening evaluation.

II. Evaluation of the Breast for Nipple Discharge Algorithm Annotations

31. Patient Presents with Nipple Discharge
    Guidelines for primary care evaluation of patient presenting with complaint of spontaneous nipple discharge are initiated with a history aimed at uncovering and characterizing any breast-related symptoms, including whether discharge has been spontaneous, pathologic, persistent, unilateral versus bilateral, single or multiple ducts, its relation to menses, pregnancy, exercise, trauma, medications, and/or thyroid disorders.

    The site around the nipple should be examined for discharge upon pressure and for a mass. Hemoccult test for blood may also be administered.

32. Assess Discharge
    Pathologic discharges are spontaneous, may be associated with a mass, and are usually bloody, blood-containing or sometimes watery (clear). They are usually unilateral, involve a single duct, and are more worrisome in patients greater than 50 years old.

    Physiologic discharges usually are bilateral, involve multiple ducts, are multicolored or milky, sticky and those that are stimulated rather than spontaneous *[R]*.

33. Single Duct or Bloody/Clear Discharge or Mass Present
    Bloody or, less commonly, clear watery discharge raises the possibility of cancer, although the most common causes of hemoccult-positive discharges are benign.

    Secretory production of fluids other than milk may be due to a pathological process in the breast. The discharge is usually unilateral and localized to a single duct, persistent and spontaneous. It can be serous, sanguineous, or serosanguineous. The most common cause of pathologic nipple discharge is a papilloma (52% to 57%). A papilloma is a papillary tumor growing from the lining of the breast duct. The discharge associated with a papilloma can be clear or grossly bloody. Solitary papillomas can harbor areas of atypia or ductal carcinoma in situ (DCIS). Although there is some debate in the literature, the standard recommendation for management of papillomas is that they be excised whenever they are diagnosed (by core needle biopsy). The remainder of cases are caused by ductal ectasia or fibrocystic changes (14% to 32%). Malignancy is found in 5% to 15% of cases of pathologic nipple discharge. The most common malignancy associated with nipple discharge in the absence of other findings is DCIS. Age is predictive of the risk of cancer in women with nipple discharge. In one series of women with isolated nipple discharge, malignancy was present in 3% of those <40 years of age, 10% of those 40 to 60 years of age, and 32% of those over 60.

    Bloody or clear discharge needs further evaluation to determine the etiology.

34. Perform Mammogram and Ultrasound
    A mammogram and ultrasound should be obtained with presence of bloody or clear discharge to rule out malignancy. An ultrasound may be helpful to locate an intraductal nodule or duct ectasia to best characterize the lesion, and then be referred to surgery if appropriate. Make certain that all recommendations for additional views, ultrasound examinations, and follow-up studies have been obtained prior to referral to surgery.

    Malignancy is found in 5% to 15% of cases of pathologic nipple discharge. The most common malignancy associated with nipple discharge in the absence of other findings is DCIS. Age is predictive of the risk of cancer in women with nipple discharge.

35. Refer to Surgeon (+/- Ductography/Magnetic Resonance Imaging [MRI] Ductography)
    Most pathologic nipple discharges should be treated with duct excision. The use of ductography and/or MRI ductography is dependent on the decision of the surgeon and radiologist.

36. Milky, Yellow, Brown, Green, Gray Discharge or Multiple Ducts
    The appearance of the fluid generally correlates with the cause. Yellow, brown, green, or gray fluid is associated with fibrocystic change in most patients. Purulent discharge can result from duct ectasia or partial duct obstruction.

38. Hormonal Evaluation
    Obtain prolactin and thyroid stimulating hormone (TSH) levels to determine an endocrinologic basis for the nipple discharge. A prolactinoma

typically causes a milky or clear discharge bilaterally.

Assay should be performed for prolactin and TSH as both of these pituitary hormones may induce galactorrhea, may have a reversible cause, and may likewise reflect further underlying pathology (e.g., pituitary adenoma, hypothyroidism, etc.)

If the mammogram and the endocrinology screening studies are normal, the patient should schedule a follow-up visit at the discretion of the responsible clinician. If the hormonal evaluation shows abnormal findings, the patient should be referred to an endocrinologist for further evaluation.

III. Evaluation of Breast Pain Algorithm Annotations

40. Patient Presents with Breast Pain
The information gathered should include location and severity of pain, relationship to menstrual cycle or physical activities and hormonal influences.

As appropriate, an exam directed at the cervical and thoracic spine, chest wall and upper extremities may be helpful in assessing other causes of pain.

Breast pain is one of the most common symptoms evaluated in primary care, surgery, or specialty breast clinics. Approximately 41% to 69% of women report having experienced breast pain. Breast pain may interfere with daily activities, relationships, and quality of life.

History and Physical Exam

The symptom of breast pain prompts many patients to make an appointment for a medical examination out of concern for the possible presence of breast cancer. A patient history is directed toward identifying and characterizing breast-related symptoms. The information gathered should include location and severity of pain, relationship to physical activities or the menstrual cycle, association with redness or warmth of overlying skin, and interference with routine activities. Hormonal influences, such as pregnancy, use of contraceptives, and hormone therapy, should also be noted. Obtaining a history may also provide information identifying non-breast sources of pain. The patient should also be asked about any new medications, and those that can be associated with breast pain should be noted. Risk assessment for breast cancer should include the appropriate reproductive, medical, and family history.

A clinical examination of the breast should be performed with careful inspection and palpation of each breast, nipple-areolar complex, and regional lymph nodes. Localized, generalized, or bilateral breast tenderness should be noted. In addition to palpating the breasts while the patient is supine, examining the breasts while the patient is sitting or lying on her side may allow breast and chest wall tenderness to be distinguished.

Laboratory studies are generally not useful. A pregnancy test, however, should be considered in women of reproductive age if the history or examination suggests pregnancy. Other hormone levels (e.g., estrogen, progesterone, and prolactin) are typically normal in patients with breast pain.

Breast pain may occur as a result of pregnancy, mastitis, trauma, thrombophlebitis, macrocysts, benign tumors, or cancer; however, only a minority of breast pain is explained by these conditions. Most breast pain is of unknown cause. A variety of conditions can result in pain perceived in the breast. A variety of conditions can be revealed as a result of a directed history and physical. As appropriate, an exam directed at the cervical and thoracic spine, chest wall, shoulders and upper extremities, sternum, heart, lungs, and abdomen may be helpful in assessing other potential causes of the pain.

Breast pain is commonly categorized into three classifications:

- Cyclic mastalgia occurs in premenopausal women and is clearly related to the menstrual cycle. The pain is typically bilateral and diffuse, often located in the upper outer quadrants of the breasts with frequent radiation to the axilla and the ipsilateral arm. Occasionally, breast pain may be unilateral or more intense in one breast.
- Non-cyclic mastalgia may involve continuous or intermittent pain that does not concur with the menstrual cycle. The pain is more often unilateral and localized with the pain in the lower inner portions of the breast. Non-cyclic breast pain generally occurs in older women, with symptoms often occurring in postmenopausal women.
- Non-mammary pain may present with the symptom of breast pain. Following the history and physical exam, differentiating breast pain and pain radiating from the chest wall or another site is usually straightforward. Occasionally the origin of pain is not evident, or there are multiple origins of pain, making evaluation more challenging.

41. Mammogram if Screening Due

Imaging studies are frequently utilized in the evaluation of the breast. A mammogram should be considered especially in women with a family history of early breast cancer. The risk of malignancy after normal findings on mammographic evaluation for breast pain is about only 0.5%. It is unclear whether the pain is related to the cancer or whether this symptom initiates a breast evaluation in which an asymptomatic cancer is identified. Breast pain secondary to malignancy is typically unilateral and persistent. In these cases, imaging with directed ultrasound may be a more valuable assessment tool. Also see Annotation #9, "Is Screening Mammogram Due?," for further information.

46. Quantitative Pain Assessment
    Breast pain may be difficult to assess as the symptoms may appear and subside without provocation, with certain activities, or with the menstrual cycle. An attempt must be made to measure the amount and severity of the patient's breast pain over time, which is difficult as there is no standard unit of pain. Prospective assessment of breast pain may be a valuable tool when considering an intervention. Possible tools to document an individual's pain include pain rating instruments, a daily breast pain chart or a diary to document the occurrence and severity of pain, use of medications, and interferences with lifestyle. These tools are particularly important in making an initial diagnosis of cyclic mastalgia and response to therapy. For more information on pain assessment see the NGC summary of the ICSI guideline Assessment and Management of Chronic Pain.

48. Discuss Non-pharmacologic and/or Pharmacologic Intervention(s) through Shared Decision-Making
    The first line of treatment for breast pain is to reassure the patient that she does not have breast cancer. The risk of malignancy following a negative examination has been estimated to be only 0.5%, so reassurance following a negative evaluation is appropriate. Approximately 15% of women choose a treatment intervention to reduce the symptom of pain. During encounters for breast pain, the patient's description of the pain, quantitative assessment of the pain, and decisions regarding reassurance, follow-up, or therapeutic intervention should be documented.

    Few women will require treatment with more than reassurance and well-tolerated medications such as evening primrose oil. For those with severe, refractory breast pain, the significant side effects of some of these medications must be balanced against the potential benefit in ameliorating breast discomfort and pain.

    Non-pharmacologic interventions for breast pain are appropriate for women with breast pain. Although there has been little scientific investigation into the effectiveness of these non-pharmacologic approaches, they are frequently found to improve breast pain symptoms in clinical practice and are of low risk and expense to the patient.

    Potential Non-Pharmacologic Therapies

    Mechanical Support

    A professionally fitted support bra, irrespective of age, cup size, or underlying breast disease, has been shown to relieve breast pain even in patients who have not responded to hormonal treatments. Support bras are recommended for exercise. A soft supportive bra during sleep may also improve symptoms.

    Lifestyle Changes

    Lifestyle changes such as smoking cessation, stress reduction, and improving coping skills may be possible low-risk interventions. Hot packs, cold packs and massage may also relieve symptoms.

    The effectiveness of dietary measures is unclear. Studies have demonstrated improvement in breast pain symptoms following dietary reduction of saturated fat. Caffeine reduction or elimination has been found to be helpful by some patients, particularly those who consume large quantities of caffeine. Clinical studies have not shown this to be a consistent outcome.

    Complementary and Alternative Medicine

    Evening Primrose Oil

    Evening primrose oil is often used as an initial treatment for breast pain because of its low incidence of side effects and positive response rates for cyclic and non-cyclic pain. It is rich in gamma-linolenic acid and is believed to alter the saturated/polyunsaturated fat balance and decrease sensitivity to hormonal influences.

    Pharmacologic Interventions

    The decision whether to treat breast pain along with the selection of a particular agent to utilize requires balancing the need for symptom relief against the likelihood of medication side effects. If considering a pharmacologic therapy, consult with a specialist should be considered.

Pharmacologic interventions may include the adjustment of medications that may be contributing to breast pain, such as oral contraceptives, hormone therapy, spironolactone, and others. Eliminating or decreasing the dose of estrogen in an oral contraceptive or hormone regimen is often effective.

Analgesics

Analgesics, such as ibuprofen, may reduce breast pain.

Danazol

Danazol is approved by the United States Food and Drug Administration for fibrocystic conditions, which often cause breast pain.

Danazol relieves breast pain in 75% to 92% of women. Reported side effects are common and include hair loss, acne, decrease in voice pitch, weight gain, irregular menses, and depression. There may also be a possible increase in venous thromboembolic events. Barrier contraception must be utilized. Danazol administered in the luteal phase only has been found to relieve premenstrual breast pain in women with premenstrual syndrome with minimal side effect. It was not effective for other premenstrual syndrome symptoms. According to the package labeling, thromboembolism, thrombotic and thrombophlebitic events have been reported including life-threatening or fatal strokes. Peliosis hepatitis and benign hepatic adenoma have also been reported with long-term use. Danazol may cause benign intracranial hypertension. Pregnancy must be ruled out prior to treatment.

Bromocriptine

One of the few hormonal abnormalities detected in breast pain has been an increase in thyrotropin induced prolactin secretion. Bromocriptine has been shown to decrease serum prolactin levels in normal and hyperprolactinemic women and may decrease dynamic secretion of prolactin in cyclic mastalgia patients. In several European studies, bromocriptine has shown significant decreases in breast pain (approximately 54%), as well as heaviness and tenderness in the breasts. Prolactin levels decline during therapy while estrogen, progesterone, testosterone, and gonadotropin releasing hormones do not significantly change. Side effects are common and dose related, including nausea, vomiting, headache, dizziness, and fatigue. The beneficial effects lasted three to six months after bromocriptine was discontinued.

Tamoxifen

Tamoxifen is a selective estrogen receptor modulator (SERM) utilized for the prevention and treatment of breast cancer. Response rates have demonstrated tamoxifen to be effective in reducing pain in 75% to 90% women with cyclic and 56% of women with non-cyclic mastalgia in controlled trials. Tamoxifen has significant side effects, with the principle concerns being from thromboembolic disease and endometrial cancer. Additional side effects include hot flashes, nausea, menstrual irregularity, and vaginal dryness or discharge. Tamoxifen, like other hormonal interventions, should be reserved for women with severe mastalgia. Contraception must be utilized. In 2002, the Food and Drug Administration added a boxed warning stating that serious and life-threatening events (including stroke, pulmonary emboli and uterine malignancy) have occurred at an incidence greater than placebo during use for cancer risk reduction.

FDA Web site

Other Medications

Other medications that have been found to be effective for the treatment of breast pain include goserelin, gestrinone, buserelin, leuprolide, quinagolide, cabergoline, thyroxine, and topical nonsteroidal anti-inflammatory agents. Gestrinone, buserelin and quinagolide are not readily available within the United States. Medroxyprogesterone has shown variable results in the treatment of breast pain. In general, antibiotics, diuretics, and most vitamins have not been effective in the treatment of breast pain.

IV. Radiologic Evaluation of the Breast Algorithm Annotations

50. Abnormal Screening or Diagnostic Mammogram
It is recommended that an abnormal finding on routine mammography be evaluated under the direction of a radiologist.

Patients referred to the department of radiology most commonly enter for screening mammography. However, patients will occasionally be referred for diagnostic mammography based on the presence of symptoms or findings on examination. In the event of an abnormal finding on mammography, it is recommended that a complete evaluation be undertaken within the department of radiology under the direction of a radiologist in order that a full characterization of the lesion will be provided back to the primary care physician ordering the original study. It will be the responsibility of the radiologist to complete the radiologic assessment of the patient within the department of radiology so that the best possible characterization of the abnormality may be provided to the primary care physician in an expeditious fashion. Any

recommendations for referral to the department of surgery for possible biopsy should be made directly to the primary care physician. However, the ultimate responsibility to make the referral will rest with the primary care clinician.

51. Additional Mammographic Studies and/or Ultrasound if Needed
    Upon obtaining an abnormal finding on a mammogram, the radiologist will determine whether further mammographic images or ultrasound are required for completion of the evaluation process. Additional projections, spot compression, magnification and/or ultrasound may be necessary to obtain further characterization of indeterminate lesions of the breast. In the event that a soft tissue mass is identified on the mammogram, further studies with ultrasound are required to determine its relative risk for malignancy. These additional studies should be done with the radiologist present, to reduce the risk of patient recall for further studies necessary to evaluate the same lesion and to allow for ultrasound directed intervention such as cyst aspiration if indicated.

52. Sort Abnormalities
    Upon completion of these views, each and every abnormality uncovered for each independent lesion of the breast studied should be sorted according to the nature of the abnormality. The radiologist should classify the lesion as representing either suspicious microcalcifications, architectural distortion, or a soft tissue mass. In the event that a soft tissue mass is identified in the mammogram, further studies are required to determine its relative risk for malignancy. Should the mass not be immediately suspicious for cancer, an ultrasound should be performed (if not already done) to determine whether or not the lesion is solid.

    In certain circumstances where diagnosis is difficult, a functional exam, either breast MRI or nuclear (molecular) imaging may be suggested by the radiologist or surgeon to sort out inconclusive cases. These cases may include:

    - Those with mammographic or ultrasound findings of uncertain significance (such as scar versus tumor)
    - Multiple lesions
    - Metastatic lymph nodes with no known primary
    - Suspicious clinical findings without imaging abnormality
    - The presence of silicone injections/implants or other problematic issues

55. Repeat Mammogram and/or Ultrasound in 6-12 Months
    If further mammographic studies or sonography demonstrate findings that are felt to be Probably Benign, a repeat image of the breast at 6 months is warranted to document stability of low-risk, probably benign lesions. The term Probably Benign is an assessment category from the Breast Imaging and Reporting Data System (BI-RADS). If the six-month mammogram is felt to be benign, return in 6 months for yearly screening mammography.

    BI-RADS Descriptors

    - BI-RADS 0: Incomplete. Needs additional imaging.
    - BI-RADS 1: Negative.
    - BI-RADS 2: Benign findings.
    - BI-RADS 3: Probably benign. Short-interval follow-up.
    - BI-RADS 4: Suspicious finding. Consider biopsy.
    - BI-RADS 5: Highly suspicious for malignancy. Take appropriate action.

    If BI-RADS descriptors are used appropriately, lesions placed in the BI-RADS 3 - Probably Benign category have a rate of malignancy lower than 2% (0.5% to 1.7%). Short-term imaging follow-up (6-month intervals for 2 years) will identify by interval progression almost all of the few lesions that actually are malignant. These cancers still have a very favorable prognosis at the time of diagnosis being early-stage cancers. The recommendation for surveillance should be given to the patient in person, immediately after completion of the full imaging workup, while the patient is still in the radiology department and should be done by the radiologist or radiology technologist who is sufficiently knowledgeable to provide a competent explanation of the rationale behind surveillance. Direct discussion with the patient should help to alleviate anxiety and also further ensure compliance.

56. Return to Screening Mammography/Report to Ordering Clinician
    If the lesion is of benign findings, the patient should be referred back to the screening process and completion of this evaluation should be reported to the ordering clinician. Refer to Annotation #9, "Is Screening Mammogram Due?," for mammography screening intervals.

V. Image-Directed Core Needle Biopsy Algorithm Annotations

57. Patient Referred for Image-Directed Biopsy
    Recommendation:

- Large core image-guided breast biopsy should be performed for biopsy of non-palpable breast masses and abnormal calcifications.

Patients referred for biopsy based on the presence of a mammographic and/or sonographic MRI nuclear molecular imaging finding that is suspicious for or highly suggestive of malignancy will undergo either conventional open excisional biopsy or large core needle biopsy.

Large core imaging-guided breast biopsy is now the technique of choice in most institutions in the United States for biopsy of non-palpable breast masses and abnormal calcifications based on decreased cost and less invasiveness. Either stereotactic or ultrasound-guided breast biopsy may be used for reliable diagnosis of breast cancer. Stereotactic guidance is preferable for biopsy of calcifications. Most solid breast masses are amenable to large core needle biopsy with either stereotactic or ultrasound guidance. The location of the lesion, its visibility at ultrasound, equipment availability and the radiologist's expertise will determine the approach selected.

Large core image-guided needle breast biopsy is recommended for tissue diagnosis in cases of obvious cancer, as it is less invasive and saves the patient an additional surgical procedure, is more cost effective and expedites the diagnostic process.

Current Changes in Breast Disease Diagnosis

Over the past 20 years, advances in mammographic and sonographic technology have established a new subspecialty in radiology. Image-guided, vacuum-assisted breast biopsy, and core needle biopsy under image guidance have changed diagnostic breast biopsy from a surgical open biopsy to image-guided needle biopsy.

The following percutaneous techniques have been developed over the past 15 years:

- Fine-needle aspiration (FNA):
  A 22- to 24-gauge needle is used for cytology. This is best used with a cytopathology department. It is also used in abnormal cyst aspiration (where fluid is obviously benign). FNA has limited use in most community hospitals because of inadequate specimens (in 30% to 40% of FNA biopsies). Therefore, large core image-directed breast biopsy has replaced most FNA biopsies.

- Core needle biopsy (CNB):
  Spring-loaded devices are used for image-guided biopsies more than any other percutaneous needle. They may be used with solid lesions of any size, under ultrasound guidance.

- Vacuum-assisted large core image-guided biopsy under stereotactic guidance:
  Vacuum-assisted needles, 8-, 9-, 11- or 12-gauge are used for microcalcifications, small masses or architectural distortion. Larger, vacuum-assisted electro-cautery devices may be used. These larger needles may help with avoiding undersampling and atypia diagnostic problems.

59. Definitive Therapy
    If cancer is diagnosed, definitive therapy may be performed on the basis of stereotactic or image-guided needle biopsy alone.

61. Surgical Consult
    Any questionable pathologic findings or pathologic findings that do not correlate with the imaging are indications for repeat biopsy by excision to rule out the presence of occult malignancy in the region of the mammographic abnormality.

63. Rebiopsy by Core or Excisional Biopsy
    The original specimen (pathology block) can be reexamined and recut for pathology exam if calcifications were noted. If calcifications cannot be demonstrated mammographically in the specimen, repeat biopsy, excisional or stereotactic, is necessary to assure that the abnormal mammographic lesion has been sampled. Biopsy must be repeated until the calcifications can be confirmed in the specimen.

65. Resume Screening Mammography
    If the mass is a fibroadenoma, then follow up with mammogram or ultrasound in 6 to 12 months. However, if the patient is experiencing extreme pain and/or extreme tenderness, the fibroadenoma may be surgically removed or undergo cryotherapy.

66. Mammogram and/or Ultrasound Follow-Up as Recommended by Radiologist
    Patients who have benign results from stereotactic or image-guided biopsy may have a repeat mammogram and/or ultrasound. The radiologist should correlate the pathology results with the mammographic/sonographic abnormalities for all patients. If they do not correlate, rebiopsy with image-directed core needle or excisional biopsy is necessary.

68. Excisional Biopsy or Repeat Image-guided Core Needle Biopsy
    Any lesion which has grown or has become more dense on mammography, despite a previous benign core biopsy, must be rebiopsied or excised to rule out cancer.

69. Inform Patient of Next Screening Date
    Refer to Annotation #9, "Is Screening Mammogram Due?," for mammography screening intervals.

Definitions:

Quality of Evidence and Strength of Recommendations

Category	Quality Definitions	Strong Recommendation	Weak Recommendation
High Quality Evidence	Further research is very unlikely to change the work group's confidence in the estimate of effect.	The work group is confident that the desirable effects of adhering to this recommendation outweigh the undesirable effects. This is a strong recommendation for or against. This applies to most patients.	The work group recognizes that the evidence, though of high quality, shows a balance between estimates of harms and benefits. The best action will depend on local circumstances, patient values or preferences.
Moderate Quality Evidence	Further research is likely to have an important impact on the work group's confidence in the estimate of effect and may change the estimate.	The work group is confident that the benefits outweigh the risks, but recognizes that the evidence has limitations. Further evidence may impact this recommendation. This is a recommendation that likely applies to most patients.	The work group recognizes that there is a balance between harms and benefit, based on moderate quality evidence, or that there is uncertainty about the estimates of the harms and benefits of the proposed intervention that may be affected by new evidence. Alternative approaches will likely be better for some patients under some circumstances.
Low Quality Evidence	Further research is very likely to have an important impact on the work group's confidence in the estimate of effect and is likely to change. The estimate or any estimate of effect is very uncertain.	The work group feels that the evidence consistently indicates the benefit of this action outweighs the harms. This recommendation might change when higher quality evidence becomes available.	The work group recognizes that there is significant uncertainty about the best estimates of benefits and harms.

Supporting Literature

In addition to evidence that is graded and used to formulate recommendations, additional pieces of literature will be used to direct the reader to other topics of interest. This literature is not given an evidence grade and is instead used as a reference for the associated topic and is found in the references section of the original guideline document.

Clinical Algorithm(s)

The following detailed and annotated clinical algorithms are provided in the original guideline document :

- Evaluation by Primary Care of Patient with Symptoms of Potential Breast Disease (Main Algorithm)
- Evaluation of Breast Mass
- Evaluation of the Breast for Nipple Discharge
- Evaluation of Breast Pain
- Radiologic Evaluation of the Breast
- Image-Directed Core Needle Biopsy

Scope

Disease/Condition(s)

Breast disease, including breast cancer

Guideline Category

Diagnosis

Evaluation

Management

Risk Assessment

Screening

Treatment

Clinical Specialty

Family Practice

Internal Medicine

Obstetrics and Gynecology

Oncology

Radiology

Surgery

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Health Care Providers

Health Plans

Hospitals

Managed Care Organizations

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To reduce the length of time between first knowledge of a breast abnormality and diagnostic resolution
- To ensure that patients with bloody or clear discharge have a mammogram (with or without an ultrasound) and are referred to a surgeon or radiologist
- To ensure that needle biopsies demonstrating abnormal findings are followed by performance of an excisional biopsy
- To ensure that all women with a breast concern that is indeterminate will have follow-up clinical assessment within 6 to 12 months

Target Population

All average risk patients who have a breast concern or abnormality

Interventions and Practices Considered

1. History and physical exam for breast-related symptoms and assessment of risk factors
2. Screening mammogram, if due
3. Diagnostic mammogram and ultrasound for palpable breast mass
4. Aspiration of simple, uncomplicated cyst
5. Assessment of nipple discharge (e.g., bloody, clear, color, milky, single or multiple ducts) and hormonal evaluation (prolactin, thyroid-stimulating hormone)
6. Referral of patient with nipple discharge to surgeon with or without ductography/magnetic resonance imaging ductography
7. Quantitative assessment of breast pain
8. Ultrasound evaluation of focal, persistent breast pain
9. Pharmacologic and non-pharmacologic treatment of breast pain
10. Image-directed core needle biopsy if breast cancer is suspected
11. Definitive therapy for breast cancer
12. Surgical consult for questionable pathologic findings
13. Rebiopsy by core or excisional biopsy
14. Mammogram or ultrasound follow-up
15. Resumption of routine mammography schedule

Major Outcomes Considered

- Risk for malignancy in patients with biopsy-proven ductal hyperplasia with atypia
- Effectiveness of pharmacologic and non-pharmacologic interventions in treating breast pain

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A literature search of clinical trials, meta-analyses, and systematic reviews is performed.

A consistent and defined process is used for literature search and review for the development and revision of Institute for Clinical Systems Improvement (ICSI) guidelines. Literature search terms for the current revision of this document include diagnosis of breast disease, MRI, mammography, breast pain and breast discharge from August 2009 through August 2011.

In the Grading of Recommendations Assessment, Development and Evaluation (GRADE) process, evidence is gathered related to a specific question. Systematic reviews are utilized first. Further literature is incorporated with randomized control trials, observational studies, etc. The evidence addresses the same population, intervention, comparisons and outcomes.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence and Strength of Recommendations

Category	Quality Definitions	Strong Recommendation	Weak Recommendation
High Quality Evidence	Further research is very unlikely to change the work group's confidence in the estimate of effect.	The work group is confident that the desirable effects of adhering to this recommendation outweigh the undesirable effects. This is a strong recommendation for or against. This applies to most patients.	The work group recognizes that the evidence, though of high quality, shows a balance between estimates of harms and benefits. The best action will depend on local circumstances, patient values or preferences.
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Supporting Literature

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Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Guideline Development Process

A workgroup consisting of 6 to 12 members that includes physicians, nurses, pharmacists, and other healthcare professionals relevant to the topic,

along with an Institute for Clinical Systems Improvement (ICSI) staff facilitator develops each document. Ordinarily, one of the physicians will be the leader. Most work group members are recruited from ICSI member organizations, but if there is expertise not represented by ICSI members, one or two members may be recruited from medical groups or hospitals outside of ICSI.

The work group will meet for 7 to 8 three-hour meetings to develop the guideline. A literature search and review is performed and the work group members, under the coordination of the ICSI staff facilitator, develop the algorithm and write the annotations and footnotes and literature citations.

Once the final draft copy of the guideline is developed, the guideline goes to the ICSI members for critical review.

Rating Scheme for the Strength of the Recommendations

See the "Rating Scheme for the Strength of the Evidence" field.

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

Critical Review Process

Every newly developed guideline or a guideline with significant change is sent to Institute for Clinical Systems Improvement (ICSI) members for Critical Review. The purpose of critical review is to provide an opportunity for the clinicians in the member groups to review the science behind the recommendations and focus on the content of the guideline. Critical review also provides an opportunity for clinicians in each group to come to consensus on feedback they wish to give the work group and to consider changes necessary across systems in their organization to implement the guideline.

All member organizations are expected to respond to critical review guidelines. Critical review of guidelines is a criterion for continued membership within the ICSI.

After the critical review period, the guideline work group reconvenes to review the comments and make changes as appropriate. The work group prepares a written response to all comments.

Approval

Each guideline, order set, and protocol is approved by the appropriate steering committee. There is one steering committee each for Respiratory, Cardiovascular, Women's Health, and Preventive Services. The Committee for Evidence-based Practice approves guidelines, order sets, and protocols not associated with a particular category. The steering committees review and approve each guideline based on the following:

- Member comments have been addressed reasonably.
- There is consensus among all ICSI member organizations on the content of the document.
- Within the knowledge of the reviewer, the scientific recommendations within the document are current.
- When evidence for a particular recommendation in the guideline has not been well established, the work group identifies consensus statements that were developed based on community standard of practice and work group expert opinion.
- Either a critical review has been carried out, or to the extent of the knowledge of the reviewer, the changes proposed are sufficiently familiar and sufficiently agreed upon by the users that a new round of critical review is not needed.

Once the guideline, order set, or protocol has been approved, it is posted on the ICSI Web site and released to members for use. Guidelines, order sets, and protocols are reviewed regularly and revised, if warranted.

Revision Process of Existing Guidelines

ICSI scientific documents are revised every 12 to 36 months as indicated by changes in clinical practice and literature. Every 6 months, ICSI checks with the work group to determine if there have been changes in the literature significant enough to cause the document to be revised earlier than scheduled.

Prior to the work group convening to revise the document, ICSI members are asked to review the document and submit comments. During revision, a literature search of clinical trials, meta-analyses, and systematic reviews is performed and reviewed by the work group. The work group will meet for 1 to 2 three-hour meetings to review the literature, respond to member organization comments, and revise the document as appropriate.

If there are changes or additions to the document that would be unfamiliar or unacceptable to member organizations, it is sent to members to review prior to going to the appropriate steering committee for approval.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

- Appropriate and timely identification and diagnosis of breast abnormalities
- Earlier detection of breast disease
- Reduced morbidity and mortality associated with breast cancer

Potential Harms

Side Effects of Medications

- Danazol may cause hair loss, acne, decrease in voice pitch, weight gain, irregular menses, and depression. There may also be a possible increase in venous thromboembolic events. Barrier contraception must be utilized. According to the package labeling, thromboembolism, thrombotic and thrombophlebitic events have been reported including life-threatening or fatal strokes. Peliosis hepatitis and benign hepatic adenoma have also been reported with long-term use. Danazol may cause benign intracranial hypertension. Pregnancy must be ruled out prior to treatment.
- Side effects of bromocriptine are dose related and include nausea, vomiting, headache, dizziness, and fatigue.
- Tamoxifen has significant side effects with the principle concerns being from thromboembolic disease and endometrial cancer. Additional side effects include hot flashes, nausea, menstrual irregularity, and vaginal dryness or discharge. Tamoxifen, like other hormonal interventions, should be reserved for women with severe mastalgia. Contraception must be utilized. In 2002, the Food and Drug Administration added a boxed warning stating that serious and life-threatening events (including stroke, pulmonary emboli and uterine malignancy) have occurred at an incidence greater than placebo during use for cancer risk reduction.
- In patients who receive gadolinium contrast media used in magnetic resonance imaging (MRI), there is the potential for renal toxicity and the rare complication (3% to 5% risk in patients with moderate to end-stage renal disease) of life-threatening nephrogenic systemic fibrosis. It is recommended that gadolinium use be avoided when possible in patients with advanced renal disease.

Disadvantages of Diagnostic Procedures

Because of the high rate of false positives, MRI screening should be recommended only to women at high risk of breast cancer.

Qualifying Statements

Qualifying Statements

- This guideline is designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients and is not intended either to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.
- This clinical guideline should not be construed as medical advice or medical opinion related to any specific facts or circumstances. Patients are urged to consult a health care professional regarding their own situation and any specific medical questions they may have. In addition, they should seek assistance from a health care professional in interpreting this guideline and applying it in their individual case.

Implementation of the Guideline

Description of Implementation Strategy

Once a guideline is approved for general implementation, a medical group can choose to concentrate on the implementation of that guideline. When four or more groups choose the same guideline to implement and they wish to collaborate with others, they may form an action group.

In the action group, each medical group sets specific goals they plan to achieve in improving patient care based on the particular guideline(s). Each medical group shares its experiences and supporting measurement results within the action group. This sharing facilitates a collaborative learning environment. Action group learnings are also documented and shared with interested medical groups within the collaborative.

Currently, action groups may focus on one guideline or a set of guidelines such as hypertension, lipid treatment, and tobacco cessation.

Detailed measurement strategies are presented in the original guideline document to help close the gap between clinical practice and the guideline recommendations. Summaries of the measures are provided in the National Quality Measures Clearinghouse (NQMC).

Implementation Recommendations

Prior to implementation, it is important to consider current organizational infrastructure that address the following:

- System and process design
- Training and education
- Culture and the need to shift values, beliefs and behaviors of the organization

The following system changes were identified by the guideline work group as key strategies for health care systems to incorporate in support of the implementation of this guideline.

1. *Primary Care, Radiology, and Surgery*
   Establish a communication plan to include all clinicians involved in the patient's treatment plan:
   - Patients undergoing biopsy should have results reported to the radiologist and/or surgeon performing the procedure as well as the primary care clinician.
2. *Primary Care*
   Establish a system for education of all female patients regarding age-appropriate mammographic screening intervals.

   Develop a system for timely assessment of breast symptoms including necessary imaging studies, follow-up, and referral to radiology or surgery for biopsy.
3. *Radiology*
   Establish a process that ensures that abnormalities of the breast are accurately identified and sorted, and that all appropriate radiologic imaging studies necessary to the evaluation process are efficiently completed.
4. *Surgery*
   Establish a process for timely completion of evaluation of breast lesions and provide additional surgical breast consultation as needed.
5. *Documentation*
   Develop a system to document time frame from receipt of pathology to patient information.

- Telephone call documentation

Implementation Tools

Clinical Algorithm

Quality Measures

Quick Reference Guides/Physician Guides

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Related NQMC Measures

Diagnosis of breast disease: percentage of BI-RADS category 4 or BI-RADS category 5 mammograms that are followed by a biopsy within 7 to 10 days.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Institute for Clinical Systems Improvement (ICSI). Diagnosis of breast disease. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2012 Jan. 45 p. [65 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

1994 Jan (revised 2012 Jan)

Guideline Developer(s)

Institute for Clinical Systems Improvement - Nonprofit Organization

Guideline Developer Comment

Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Organizations participating in the Institute for Clinical Systems Improvement (ICSI): Affiliated Community Medical Centers; Allina Medical Clinic; Aspen Medical Group; Baldwin Area Medical Center; Brown Clinic; Center for Diagnostic Imaging/Medical Scanning Consultants; CentraCare; Central Lakes Medical Clinic; Chippewa County – Montevideo Hospital & Clinic; Cuyuna Regional Medical Center; Essentia Health; Fairview Health Services; Family HealthServices Minnesota; Family Practice Medical Center; Fergus Falls Medical Clinic; Gillette Children's Specialty Healthcare; Grand Itasca Clinic and Hospital; Hamm Clinic; HealthEast Care System; HealthPartners Central Minnesota Clinics; HealthPartners Medical Group & Regions Hospital; Hennepin County Medical Center; Hennepin Faculty Associates; Howard Young Medical Center; Hudson Physicians; Hutchinson Area Health Care; Hutchinson Medical Center; Integrity Health Network; Lake Region Healthcare Corporation; Lakeview Clinic; Mankato Clinic; MAPS Medical Pain Clinics; Marshfield Clinic; Mayo Clinic; Mercy Hospital and Health Care Center; Midwest Spine Institute; Minnesota Association of Community Health Centers; Minnesota Gastroenterology; Multicare Associates; New Richmond Clinic; North Central Heart Institute; North Clinic; North Memorial Health Care; Northwest Family Physicians; Obstetrics and Gynecology Specialists; Olmsted Medical Center; Park Nicollet Health Services; Planned Parenthood Minnesota, North Dakota, South Dakota; Quello Clinic; Raiter Clinic; Rice Memorial Hospital; Ridgeview Medical Center; River Falls Medical Clinic; Riverwood Healthcare Center; South Lake Pediatrics; Southside Community Health Services; Stillwater Medical Group; University of Minnesota Physicians; Winona Health

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Guideline Committee

Committee on Women's Health

Composition of Group That Authored the Guideline

Work Group Members: Audrey Park-Skinner, MD (Work Group Leader) (Essentia Health) (Surgery); Deepti Pandita, MD (Park Nicollet Health Services) (Internal Medicine); Mary Lechner, MD (Center for Diagnostic Imaging) (Radiology); Sarah Nielsen, DO (Marshfield Clinic) (Radiology); Judy Boughey, MD (Mayo Clinic) (Surgery); Todd Morris, MD (HealthPartners Medical Group and Regions Hospital) (Surgery); Kari Retzer, RN (Institute for Clinical Systems Improvement) (Facilitator); Cindy Harper (Institute for Clinical Systems Improvement) (Systems Improvement Coordinator)

Financial Disclosures/Conflicts of Interest

In the interest of full disclosure, Institute for Clinical Systems Improvement (ICSI) has adopted a policy of revealing relationships work group members have with companies that sell products or services that are relevant to this guideline topic. It is not assumed that these financial interests will have an adverse impact on content. They are simply noted here to fully inform users of the guideline.

Mary Lechner, MD, had received speaker's fees from Dilon Technologies in 2009.

No other work group members have potential conflicts of interest to disclose.

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Institute for Clinical Systems Improvement (ICSI). Diagnosis of breast disease. Bloomington (MN): Institute for Clinical Systems Improvement (ICSI); 2010 Jan. 47 p. [65 references]

Guideline Availability

Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site .

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org ; e-mail: icsi.info@icsi.org.

Availability of Companion Documents

The following is available:

- Diagnosis of breast disease. Executive summary. Bloomington (MN): Institute for Clinical Systems Improvement, 2012 Jan. Electronic copies: Available from the Institute for Clinical Systems Improvement (ICSI) Web site .

Print copies: Available from ICSI, 8009 34th Avenue South, Suite 1200, Bloomington, MN 55425; telephone, (952) 814-7060; fax, (952) 858-9675; Web site: www.icsi.org ; e-mail: icsi.info@icsi.org.

Patient Resources

None available

NGC Status

This summary was completed by ECRI on July 10, 2000. The information was verified by the guideline developer on April 25, 2001. This summary updated on March 15, 2002. The updated information was reviewed by the guideline developer as of April 25, 2002. This summary was updated again on September 3, 2003. The information was verified by the guideline developer on November 26, 2003. This summary was updated by ECRI on May 26, 2004, and most recently on January 11, 2006. This summary was updated by ECRI Institute on May 17, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Gadolinium-based contrast agents. This summary was updated by ECRI Institute on June 20, 2007 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents. This summary was updated by ECRI Institute on March 19, 2008. This summary was most recently updated by ECRI Institute on June 23, 2010. This summary was updated by ECRI Institute on January 13, 2011 following the U.S. Food and Drug Administration (FDA) advisory on gadolinium-based contrast agents. This NGC summary was updated by ECRI Institute on May 25, 2012. This summary was updated by ECRI Institute on September 18, 2015 following the U.S. Food and Drug Administration advisory on non-aspirin nonsteroidal anti-inflammatory drugs (NSAIDs).

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